Rule 116. The Amendment is not believed to raise any new issues, and there is no need in further search by the Examiner. The issues presented by claim the amended claim 6 are the same issues that are presented by currently pending claim 6.

The Amendment was not earlier presented because applicant became familiar with new grounds for rejection only after they were first indicated in the Final Action.

By the present amendment, claim 6 is amended to more clearly define the field the present invention relates to and to correct a spelling error in claim 8.

It is respectfully submitted that amending claim 6 to more precisely specify the field of the invention does not constitute new issue. The amendment of claim 6 is based on the original disclosure (first full paragraph on page 8) and would not require an additional search in the part of the Examiner as the method has been thoroughly searched.

Based on the foregoing amendments and the following remarks, the application is deemed to be in condition for allowance, and action to that end is respectfully requested.

## I. Rejection of Claims

Ia. Rejection Under 35 U.S.C., §112, Second Paragraph

The Examiner rejected claims 1 and 5 under 35 U.S.C., §112, second paragraph, for being indefinite. Claims 1 and 5 have been cancelled by the amendment of October 3, 1996. It is respectfully submitted that claims 6-10 comply with all of the requirements of 35 U.S.C. §112.

## Ib. Rejection Over the Prior Art

The Examiner rejected claims 6-8 under 35 U.S.C. §102(b) as being anticipated by Potzscke et al., and rejected claims 6-10 under 35 U.S.C. §103(a) as being unpatentable over Potzscke et al. in view of Bonhard et al., U.S. Patent No. 4,136,093 (Bonhard).

It is respectfully submitted that claim 6 (as amended) and claims 7-10, dependent on claim 6, are patentable over the cited prior art.

Specifically, claim 6 is directed to a method for preparation of molecularly uniform hyperpolymeric hemogloblins

from a solution containing crosslinked hyperpolmeric hemoglobins molecules with a size and weight which are a hundred to several hundred times those of quarternary hyperpolymeric hemogloblins molecules.

It is known to separate proteins the size or weight of which is determined maximally by a quarternary structure on the basis of their molecular weight. The upper molecular weight range is about 500,000. (Please see page 7, para. 4 of the application as filed).

In contrast to the usually available proteins, the hemoglobin hyperpolymers on which the invention is based are giant molecules, ... the size and weight of which, depending on the degree of polymerization are a hundred to several hundred times those of the quaternary-structured hemoglobin molecule.

While the method applied for separation is known per se, it has been used for the first time on hyperpolymeric giants with very surprising results, the advantage being a successful molecular weight specific separation with giant molecules (see page 9, para 3 of the application as filed).

None of the cited references, neither the Potzschke article nor U.S. Patent 'Bonhard '093, make any reference to crosslinked hyperpolymeric hemoglobin molecules. Therefore, the subject matter of claim 6 is different from the disclosure in the cited references.

It is a long held view that the preamble is given the effect of a limitation, is deemed essential to point out the invention defined by a claim, and is "considered necessary to give life, meaning and vitality to the claims" when "there inhered in the article specified in the preamble a problem, which transcended that before prior artisans..." Kropa v. Robie and Maheman, 88 U.S.P.Q. 478, 481 (CCPA 1951).

Though the foregoing holding refers to an article, it is respectfully submitted that it is equally applicable to a method. The same court further stated "the nature of the problem characterized the elements comprising the article, and recited in the body of the claim ... following the introductory clause, so as to distinguish the claim ... over the prior art."

None of the cited references addresses the problem of preparation of molecularly uniform hyperpolymeric hemogloblins

<del>NY2-95496.1</del> 03/06/97 10:55am from a solution containing crosslinked hyperpolymeric hemoglobins molecules with a size and weight which are up to several hundred times those of quarternary hyperpolymeric hemoglobins molecules.

In view of the above, it is respectfully submitted that claim 6 patentably defines over the prior art and is, therefore, allowable.

Claims 7-10 depend on claim 6 and are allowable for the same reason claim 6 is allowable and further because of specific features recited therein which, when taken above and/or in combination with features recited in claim 6, are not disclosed or suggested in the prior art.

## CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance, and allowance of the application is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects, in order to place the

case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue.

Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

Respectfully submitted

for applicant,

David Toren

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Dated: March 7, 1997

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 2023 on March 7, 1997.